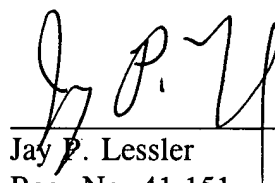


29-46 have been amended to include all of the limitations of allowable claim 21. Accordingly, this rejection is moot.

In view of the above amendments and remarks, it is respectfully requested that the application be reconsidered and all pending claims be allowed and the case passed to issue.

If there are any other issues remaining which the Examiner believes could be resolved through either a supplemental response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

Respectfully submitted

A handwritten signature in black ink, appearing to read "Jay P. Lessler", is written over a horizontal line.

Jay P. Lessler
Reg. No. 41,151
Attorney for Applicants

DARBY & DARBY
Post Office Box 5257
New York, NY 10150-5257
Phone (212) 527-7700

Mark-Up Claims
U.S. Serial No. 10/005,511
Accompanying December 16, 2002 Amendment
(Our Docket No. 1946/1B861-US2)

IN THE CLAIMS:

21. (Amended) A [The] pharmacological composition [of claim 20,]

comprising:

(A) at least one biologically-active agent; and

(B) at least one carrier compound having the formula

2-HO-Ar-CONR⁸-R⁷-COOH

or a salt thereof, wherein

Ar is a phenyl substituted with at least one of C₁-C₅ alkyl, C₂-C₄ alkenyl, -F, -Cl, -OH, -SO₂, -COOH or -SO₃H;

R⁷ is selected from the group consisting of C₄ to C₂₀ alkyl, C₄ to C₂₀ alkenyl, phenyl, naphthyl, (C₁ to C₁₀ alkyl)phenyl, (C₁ to C₁₀ alkenyl)phenyl, (C₁ to C₁₀ alkyl)naphthyl, (C₁ to C₁₀ alkenyl) naphthyl, phenyl (C₁ to C₁₀ alkyl), phenyl (C₁ to C₁₀ alkenyl), naphthyl (C₁ to C₁₀ alkyl) and naphthyl (C₁ to C₁₀ alkenyl);

R⁷ is optionally substituted with C₁ to C₄ alkyl, C₁ to C₄ alkenyl, C₁ to C₄ alkoxy, -OH, -SH and -CO₂R⁹ or any combination thereof;

R⁷ is optionally interrupted by oxygen, nitrogen, sulfur or any combination thereof;

R⁸ is selected from the group consisting of hydrogen, C₁ to C₄ alkyl, C₁ to C₄ alkenyl, hydroxy, and C₁ to C₄ alkoxy; and

R⁸ is optionally substituted with C₁ to C₄ alkyl, C₁ to C₄ alkenyl, C₁ to C₄ alkoxy, -

OH, -SH and -CO₂R⁹ or any combination thereof;

R⁹ is hydrogen, C₁ to C₄ alkyl, or C₁ to C₄ alkenyl;

with the proviso that the compounds are not substituted with an amino group in the position alpha to the acid group.

29. (Amended) The composition of claim [20] 21, wherein the biologically active agent comprises at least one peptide, hormone, polysaccharide, mucopolysaccharide, carbohydrate, or lipid.

32. (Amended) The composition according to claim [20] 21, wherein the biologically active agent comprises human growth hormone, bovine growth hormone, growth hormone-releasing hormone, an interferon, interleukin-1, interleukin-II, insulin, heparin, low molecular weight heparin, calcitonin, erythropoietin, atrial natriuretic factor, an antigen, a monoclonal antibody, somatostatin, adrenocorticotropin, gonadotropin releasing hormone, oxytocin, vasopressin, cromolyn sodium, vancomycin, desferrioxamine, parathyroid hormone, an antimicrobial, an antifungal agent or a combination thereof.

41. (Amended) A dosage unit form comprising

(A) a pharmacological composition according to claim [20] 21; and

(B) (i) an excipient,

(ii) a diluent

(iii) a disintegrant

(iv) a lubricant,

- (v) a plasticizer,
- (vi) a colorant,
- (vii) a dosing vehicle, or
- (viii) any combination thereof.

44. (Amended) A method for preparing a pharmacological composition, said method comprising mixing:

- (A) at least one biologically-active agent;
- (B) at least one carrier compound having the formula



wherein

Ar is a substituted phenyl or naphthyl;

R⁷ is selected from the group consisting of C₄ to C₂₀ alkyl, C₄ to C₂₀ alkenyl, phenyl, naphthyl, (C₁ to C₁₀ alkyl)phenyl, (C₁ to C₁₀ alkenyl)phenyl, (C₁ to C₁₀ alkyl)naphthyl, (C₁ to C₁₀ alkenyl) naphthyl, phenyl (C₁ to C₁₀ alkyl), phenyl (C₁ to C₁₀ alkenyl), naphthyl (C₁ to C₁₀ alkyl) and naphthyl (C₁ to C₁₀ alkenyl);

R⁷ is optionally substituted with C₁ to C₄ alkyl, C₁ to C₄ alkenyl, C₁ to C₄ alkoxy, -OH, -SH and -CO₂R⁹ or any combination thereof;

R⁷ is optionally interrupted by oxygen, nitrogen, sulfur or any combination thereof;

R⁸ is selected from the group consisting of hydrogen, C₁ to C₄ alkyl, C₁ to C₄ alkenyl, hydroxy, and C₁ to C₄ alkoxy; and

R⁹ is hydrogen, C₁ to C₄ alkyl, or C₁ to C₄ alkenyl;

with the proviso that the compounds are not substituted with an amino group in the position

alpha to the acid group; and

(C) optionally a dosing vehicle.

45. (Amended) A method for administering a biologically-active agent to an animal in need of said agent, said method comprising administering orally to said animal a composition as defined in claim [20] 21.

46. (Amended) A method for administering a biologically-active agent to a mammal in need of said agent, said method comprising administering orally to said mammal a composition as defined in claim [20] 21.

Pending Claims
U.S. Serial No. 10/005,511
After December 16, 2002 Amendment
(Our Docket No. 1946/1B861-US2)

21. (Amended) A pharmacological composition comprising:

- (A) at least one biologically-active agent; and
- (B) at least one carrier compound having the formula



or a salt thereof, wherein

Ar is a phenyl substituted with at least one of C₁-C₅ alkyl, C₂-C₄ alkenyl, -F, -Cl, -OH, -SO₂, -COOH or -SO₃H;

R⁷ is selected from the group consisting of C₄ to C₂₀ alkyl, C₄ to C₂₀ alkenyl, phenyl, naphthyl, (C₁ to C₁₀ alkyl)phenyl, (C₁ to C₁₀ alkenyl)phenyl, (C₁ to C₁₀ alkyl)naphthyl, (C₁ to C₁₀ alkenyl) naphthyl, phenyl (C₁ to C₁₀ alkyl), phenyl (C₁ to C₁₀ alkenyl), naphthyl (C₁ to C₁₀ alkyl) and naphthyl (C₁ to C₁₀ alkenyl);

R⁷ is optionally substituted with C₁ to C₄ alkyl, C₁ to C₄ alkenyl, C₁ to C₄ alkoxy, -OH, -SH and -CO₂R⁹ or any combination thereof;

R⁷ is optionally interrupted by oxygen, nitrogen, sulfur or any combination thereof;

R⁸ is selected from the group consisting of hydrogen, C₁ to C₄ alkyl, C₁ to C₄ alkenyl, hydroxy, and C₁ to C₄ alkoxy; and

R⁸ is optionally substituted with C₁ to C₄ alkyl, C₁ to C₄ alkenyl, C₁ to C₄ alkoxy, -OH, -SH and -CO₂R⁹ or any combination thereof;

R⁹ is hydrogen, C₁ to C₄ alkyl, or C₁ to C₄ alkenyl;

with the proviso that the compounds are not substituted with an amino group in the position alpha to the acid group.

22. The composition of claim 21 wherein Ar is a substituted phenyl.
23. The composition of claim 21, wherein Ar is a phenyl substituted with -Cl.
24. The composition of claim 21, wherein Ar is a phenyl substituted with -F.
25. The composition of claim 23, wherein R⁷ is selected from the group consisting of C₄ to C₂₀ alkyl, and C₄ to C₂₀ alkenyl, (C₁-C₁₀ alkyl)phenyl, and phenyl (C₁ to C₁₀ alkyl).
26. The composition of claim 23, wherein R⁷ is C₄-C₂₀ alkyl.
27. The composition of claim 26, wherein R⁷ is not substituted or interrupted.
28. The composition of claim 27, wherein R⁸ is hydrogen.
29. (Amended) The composition of claim 21, wherein the biologically active agent comprises at least one peptide, hormone, polysaccharide, mucopolysaccharide, carbohydrate, or lipid.

30. The composition of claim 29, wherein the biologically active agent is a peptide.

31. The composition of claim 29, wherein the biologically active agent is a mucopolysaccharide.

32. (Amended) The composition according to claim 21, wherein the biologically active agent comprises human growth hormone, bovine growth hormone, growth hormone-releasing hormone, an interferon, interleukin-1, interleukin-II, insulin, heparin, low molecular weight heparin, calcitonin, erythropoietin, atrial naturetic factor, an antigen, a monoclonal antibody, somatostatin, adrenocorticotropin, gonadotropin releasing hormone, oxytocin, vasopressin, cromolyn sodium, vancomycin, desferrioxamine, parathyroid hormone, an antimicrobial, an antifungal agent or a combination thereof.

33. The composition according to claim 32, wherein said biologically-active agent comprises human growth hormone, an interferon, insulin, heparin, low molecular weight heparin, calcitonin, erythropoietin, cromolyn sodium, parathyroid hormone, an antimicrobial or a combination thereof.

34. The composition according to claim 33, wherein said biologically-active agent comprises human growth hormone.

35. The composition according to claim 33, wherein said biologically-active agent comprises insulin.

36. The composition according to claim 33, wherein said biologically-active agent comprises heparin.

37. The composition according to claim 33, wherein said biologically-active agent comprises low molecular weight heparin.

38. The composition according to claim 33, wherein said biologically-active agent comprises calcitonin.

39. The composition according to claim 33, wherein said biologically-active agent comprises cromolyn sodium.

40. The composition according to claim 33, wherein said biologically-active agent comprises parathyroid hormone.

41. (Amended) A dosage unit form comprising

(A) a pharmacological composition according to claim 21; and

(B) (i) an excipient,

(ii) a diluent

(iii) a disintegrant

- (iv) a lubricant,
- (v) a plasticizer,
- (vi) a colorant,
- (vii) a dosing vehicle, or
- (viii) any combination thereof.

42. A dosage unit form according to claim 41, comprising a tablet, a capsule, or a liquid.

43. A dosage unit form according to claim 41, wherein said dosing vehicle is selected from the group consisting of water, 1,2-propane diol, ethanol, and any combination thereof.

44. (Amended) A method for preparing a pharmacological composition, said method comprising mixing:

- (A) at least one biologically-active agent;
- (B) at least one carrier compound having the formula



wherein

Ar is a substituted phenyl or naphthyl;

R⁷ is selected from the group consisting of C₄ to C₂₀ alkyl, C₄ to C₂₀ alkenyl, phenyl, naphthyl, (C₁ to C₁₀ alkyl)phenyl, (C₁ to C₁₀ alkenyl)phenyl, (C₁ to C₁₀ alkyl)naphthyl, (C₁ to C₁₀ alkenyl) naphthyl, phenyl (C₁ to C₁₀ alkyl), phenyl (C₁ to C₁₀ alkenyl), naphthyl (C₁ to C₁₀

alkyl) and naphthyl (C₁ to C₁₀ alkenyl);

R⁷ is optionally substituted with C₁ to C₄ alkyl, C₁ to C₄ alkenyl, C₁ to C₄ alkoxy, -OH, -SH and -CO₂R⁹ or any combination thereof;

R⁷ is optionally interrupted by oxygen, nitrogen, sulfur or any combination thereof;

R⁸ is selected from the group consisting of hydrogen, C₁ to C₄ alkyl, C₁ to C₄ alkenyl, hydroxy, and C₁ to C₄ alkoxy; and

R⁹ is hydrogen, C₁ to C₄ alkyl, or C₁ to C₄ alkenyl;

with the proviso that the compounds are not substituted with an amino group in the position alpha to the acid group; and

(C) optionally a dosing vehicle.

45. (Amended) A method for administering a biologically-active agent to an animal in need of said agent, said method comprising administering orally to said animal a composition as defined in claim 21.

46. (Amended) A method for administering a biologically-active agent to a mammal in need of said agent, said method comprising administering orally to said mammal a composition as defined in claim 21.